

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 May 2002 (30.05.2002)

PCT

(10) International Publication Number
WO 02/41771 A1

(51) International Patent Classification⁷: A61B 5/0205

[IL/IL]; 5 Brazil Street, 69460 Tel Aviv (IL). **MODAI**, Alon [IL/IL]; 44 Hakukiya Street, 75548 Rishon Le Zion (IL). **MODAI**, Oren [IL/IL]; 5 Brazil Street, 69460 Tel Aviv (IL). **MODAI**, Erez [IL/IL]; 11 Patai Street, 69973 Tel Aviv (IL).

(21) International Application Number: PCT/IL01/01072

(22) International Filing Date:
21 November 2001 (21.11.2001)

(25) Filing Language: English

(74) Agents: SANFORD T. COLB & CO. et al.; P.O. Box 2273, 76122 Rehovot (IL).

(26) Publication Language: English

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(30) Priority Data:
09/722,976 27 November 2000 (27.11.2000) US

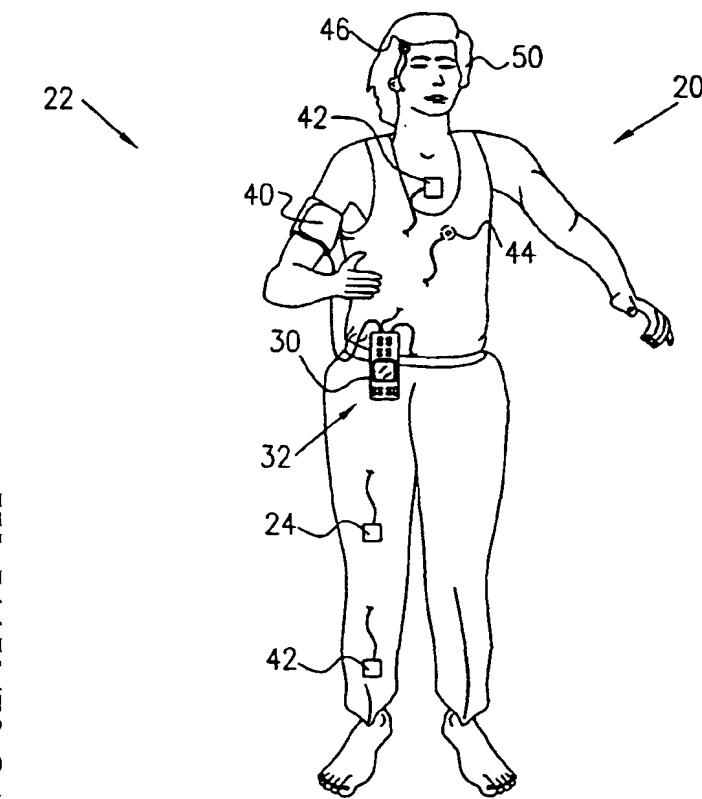
(71) Applicant (for all designated States except US): **MODCO INC.** [US/US]; Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MODAI, David**

[Continued on next page]

(54) Title: APPARATUS AND METHOD FOR MONITORING BLOOD PRESSURE AND ANOTHER PHYSIOLOGICAL PARAMETER



(57) Abstract: Apparatus (20) for monitoring a patient (50) is provided. A blood pressure sensor (40) measures blood pressure of the patient (50), substantially without restricting motion of the patient (50). A physical disposition sensor (42) measures an aspect of the physical disposition of the patient. A control unit (30) receives respective blood pressure and physical disposition signals from the blood pressure sensor (40) and the physical disposition sensor (42), and analyzes the signals in combination, so as to detect an abnormal condition of the patient (50). All signals are radio transmitted to a receiving station.

WO 02/41771 A1



(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— with international search report

APPARATUS AND METHOD FOR MONITORING BLOOD PRESSURE AND
ANOTHER PHYSIOLOGICAL PARAMETER

FIELD OF THE INVENTION

The present invention relates generally to patient monitoring, and specifically to
5 measuring and monitoring physiological parameters of a patient.

BACKGROUND OF THE INVENTION

Patients with a variety of hemodynamic pathologies, such as those receiving drug treatment for hypertension, elderly patients, diabetics, and patients with autonomic insufficiencies, often suffer severe problems resulting from an abrupt fall in blood pressure and hence in blood supply to the upper part of the body, resulting in, *inter alia*, unexpected loss of consciousness. For example, a patient may fall and fracture his/her hip, or lose control while driving a car. Standard practice to avoid these problems includes advising patients to be vigilant to imminent fainting, to lay down upon feeling light-headed, and, in extreme cases, not to drive a motor vehicle.

15 Every human being, on changing from laying down to the upright position, experiences an abrupt but typically benign diversion of a certain volume of blood from the upper to the lower part of the body. However, since the brain is located in the upper part of the body, some patients who start with an artificially-lowered blood pressure risk, among others, potentially-serious effects resulting from the sudden reduction of the cerebral blood supply. In healthy 20 individuals, these risks are avoided by the body's immediate response to the position change, including active narrowing of the great veins in the lower part of the body. This active response limits the lower body's capacity to accommodate the otherwise considerable volume of blood which gravity would divert thereto from the upper part of the body. In addition, the heart rate is accelerated, thus pumping more blood to the various organs, including the brain.

25 In a variety of pathological situations, however, one or more of the physiologic response mechanisms fail to be activated or sustained when a patient assumes the upright position. A physiologically-significant fall in blood pressure associated with such a change in position is called orthostatic hypotension (OH). Orthostatic hypotension is frequent among elderly individuals, due to age-related insufficiencies of the appropriate reflex mechanisms. 30 Moreover, a large majority of patients afflicted by OH are those who receive anti-hypertensive

drugs to treat hypertension. Most of the drugs used to treat hypertension impair one or more of the physiological mechanisms responsible for preventing OH.

In a review article by Houston, entitled, "Treatment of hypertensive urgencies and emergencies with nifedipine," *American Heart Journal*, May, 1986, 111(5), pp. 963-969, which is incorporated herein by reference, a number of disadvantages of short acting nifedipine therapy for hypertension are noted, including: "(1) Potential hypotension or normotension due to rapid effect and potency of nifedipine could reduce critical blood flow to some vital organs and induce complications, (2) Acute reversible renal deterioration may occur in patients with chronic renal insufficiency, (3) Cerebral edema and hypertensive encephalopathy may be exacerbated in some patients, and (4) [Nifedipine] may cause a precipitous fall in blood pressure when given to patients... [who take certain drugs]."

An article by Wachter, entitled, "Symptomatic hypotension induced by nifedipine in the acute treatment of severe hypertension," *Archives of Internal Medicine*, March, 1987, 147, pp. 556-558, which is incorporated herein by reference, describes three patients who developed profound hypotension after acute treatment of hypertension with standard doses of nifedipine. There were no obvious predisposing factors for this reaction.

In a letter to the editor by Messerli et al., entitled, "Sublingual nifedipine for hypertensive emergencies," *The Lancet*, October 5, 1991, 338, p. 881, which is incorporated herein by reference, the writers condemn the excessive use of short acting nifedipine to treat hypertension, based in part on the "lack of any dose-response information or any assessment of the true risk of a cataclysmic complication..." In an article by Grossman et al., entitled, "Should a moratorium be placed on sublingual nifedipine capsules given for hypertensive emergencies and pseudoemergencies?" *JAMA*, October 23-30, 1996, 276(16), pp. 1328-1331, which is incorporated herein by reference, and in an editorial in the same issue (pp. 1342-1343), entitled, "The FDA's decisions regarding new indications for approved drugs: Where's the evidence?" which is also incorporated herein by reference, arguments indicating against the use of short acting nifedipine in the treatment of hypertension which are similar to those described in the above-cited Messerli article are discussed.

An article by Slavachevsky et al., entitled, "Effect of enalapril and nifedipine on orthostatic hypotension in older hypertensive patients," *Journal of the American Geriatric Society*, July, 2000, 48(7), pp. 807-810, which is incorporated herein by reference, compares the effect of enalapril and long-acting nifedipine on orthostatic hypotension in older patients.

Supine and standing blood pressure measurements were recorded at zero, one, and five minutes after each treatment.

In still another article, entitled "Management of severe orthostatic hypotension by head-up-tilt posture and administration of fludrocortisone," by Kardos et al., *Orv. Hetil.* (Hungarian), October, 1996, 137(43), pp. 2407-2411, which is incorporated herein by reference, a case study of a patient with recurrent episodes of syncope is described. Imposed changes to the patient's posture during sleeping periods are reported as being related to decreased incidence of syncope.

In yet another article, entitled "Cerebral versus systemic hemodynamics during graded orthostatic stress in humans," by Levine et al., *Circulation*, July, 1994, 90(1), pp. 298-306, which is incorporated herein by reference, cerebral vasoconstriction in healthy humans was measured in response to applied lower body negative pressure (LBNP).

In an article by Ledingham and Rajagopalan, entitled, "Cerebral complications in the treatment of accelerated hypertension," *Quarterly Journal of Medicine, New Series XLVIII*, January, 1979, 189, pp. 25-41, which is incorporated herein by reference, the authors describe "[t]en patients with accelerated hypertension, ...in whom abnormal neurological signs developed following the rapid reduction of arterial pressure. Three patients died without recovering from the neurological damage. A fourth died of an unrelated cause. ... Areas of ischaemic damage were found in the brains of three of these cases. Of the six survivors, four were left with some permanent neurological disability. It is likely that these changes resulted from the inability of the cerebral circulation in patients with severe hypertension to autoregulate blood flow to the brain, so that a rapid reduction in arterial pressure led to ischaemia..."

Cove et al., in an article entitled, "Blindness after treatment for malignant hypertension," *British Medical Journal*, July 28, 1979, pp. 245-246, which is incorporated herein by reference, report about two patients who became blind after drug treatment for malignant hypertension. In an editorial in the same issue, entitled, "Dangerous antihypertensive treatment" (pp. 228-229), which is also incorporated herein by reference, the results of the Cove article are discussed, as well as other adverse responses to administering certain forms of pharmaceutical therapy in the treatment of hypertension.

In a report by Nobile-Orazio and Sterzi, entitled, "Cerebral ischaemia after nifedipine treatment," *British Medical Journal*, October 10, 1981, 283, p. 948, which is incorporated herein by reference, the authors relate details of a 67-year-old woman to whom short acting

nifedipine was added to the treatment regimen for chronic hypertension. On the second day, two hours after taking the nifedipine, she suddenly lost consciousness, and later complained of headache, drowsiness, and vertigo. On examination, she was found to have signs of cerebellar dysfunction, and subendocardial ischemia.

5 Jaker et al., in an article entitled, "Oral nifedipine vs oral clonidine in the treatment of urgent hypertension," *Archives of Internal Medicine*, February, 1989, 149, pp. 260-265, which is incorporated herein by reference, report that subjective side effects to nifedipine include mild headache, lightheadedness, and drowsiness. Subjective responses to clonidine included sedation and complaints of dry mouth. An editorial discussing the Jaker article, entitled, 10 "How urgent is 'urgent' hypertension," on page 257 of the same issue, which is incorporated herein by reference, argues that an abrupt reduction of blood pressure by nifedipine may precipitate or exacerbate ischemic heart disease.

In response to the Jaker article, a letter to the editor by Schwartz et al., entitled, "Oral nifedipine in the treatment of hypertensive urgency: Cerebrovascular accident following a 15 single dose," *Archives of Internal Medicine*, March, 1990, 150, pp. 686-687, which is incorporated herein by reference, discusses adverse reactions to a dose of nifedipine administered to a hypertensive patient. The letter notes that the "pathogenesis of cerebrovascular accidents following administration of nifedipine is probably related to the rapid lowering of blood pressure, though hypotensive values have not been reached. When 20 arteriosclerotic narrowing of cerebral arteries is present, poststenotic hypotension results that may exhaust the vasodilatory reserve in the more distal arteries. Under these circumstances, sudden lowering of blood pressure by nifedipine may provoke cerebral ischemia, which cannot be compensated by additional vasodilatation in distal arteries." In a reply written by Jaker, it is stated, "Rapid reduction of blood pressure even to normotensive levels may be associated 25 with neurologic sequelae or cardiac ischemia, particularly in patients who are volume depleted,... patients who are elderly, and patients who are being treated with nitrates."

In an article by Zeller et al., entitled, "Rapid reduction of severe asymptomatic hypertension," *Archives of Internal Medicine*, October, 1989, 149, pp. 2186-2189, which is incorporated herein by reference, clinical results are reported with respect to various 30 antihypertensive therapies. In addition, Zeller et al. interpret data from articles by Strandgaard to indicate that "...autoregulation of cerebral blood flow in chronically hypertensive patients occurs at a far higher range of pressures than in normotensive persons and that cerebral perfusion may fall at arterial pressures generally considered adequate" ("Autoregulation of

cerebral blood flow in hypertensive patients: The modifying influence of prolonged antihypertensive treatment on the tolerance to acute, drug-induced hypotension," Strandgaard, *Circulation*, 1976, 53, pp. 720-728, and "Autoregulation of brain circulation in severe arterial hypertension," Strandgaard et al., *British Medical Journal*, 1973, 1, pp. 507-510, both of which are incorporated herein by reference).

An article by Davidson et al., entitled, "Drug-related syncope," *Clinical Cardiology*, October, 1989, 12(10), pp. 577-580, which is incorporated herein by reference, discusses an analysis of 41 patients who were admitted to the emergency room because of drug-related syncope. Thirty-eight of these patients experienced symptomatic orthostatic hypotension following taking a drug.

In an article by Kanada et al., entitled, "Angina-like syndrome with diazoxide therapy for hypertensive crisis, *Annals of Internal Medicine*, 1976, 84, pp. 696-699, which is incorporated herein by reference, a large fraction of patients are reported to develop significant electrocardiographic changes, as well as substernal discomfort, secondary to rapid reduction of high blood pressure by diazoxide for hypertension. Kanada's findings are interpreted to indicate that myocardial ischemia developed in response to a sudden, severe, drug-related drop in blood pressure.

In an article by Aromatorio et al., entitled, "Hypotension and sinus arrest with nifedipine in pulmonary hypertension," *Chest*, February, 1985, 87(2), pp. 265-267, which is incorporated herein by reference, a case of sinus arrest secondary to the acute administration of short acting sublingual nifedipine is reported.

In response to a report by O'Malia et al., entitled, "Nifedipine-associated myocardial ischemia or infarction in the treatment of hypertensive urgencies," *Annals of Internal Medicine*, August, 1987, 107(2), which is incorporated herein by reference, Leavitt and Zweifler replied in a letter in the February, 1988, issue of the same journal (p. 5), stating that "...some patients are at risk of myocardial injury even though they have no history of coronary artery disease. Of particular concern should be elderly patients, especially those with an 'atherosclerotic' component to their hypertension (pulse greater than 100/minute) and patients likely to have 'silent ischemia' such as those with diabetes mellitus." A second letter in the February issue, by Meriden (pp. 305-306) asks regarding the patients in the O'Malia article, "[D]id any of these patients have volume depletion, diabetes mellitus, postural hypotension, or autonomic neuropathy before treatment with sublingual nifedipine...? Any of the above conditions can worsen the risk of postural hypotension or potentiate a severe drop in blood

pressure when potent and effective drugs such as nifedipine are used." Both of these letters are also incorporated herein by reference.

5 Timmis et al., in an article entitled, "Restoration of normal reflex responses to orthostatic stress during felodipine therapy in congestive heart failure," *Cardiovascular Research*, October, 1984, 18(10), pp. 613-619, which is incorporated herein by reference, discuss the effects of vasodilator therapy on orthostatic reflexes in patients with congestive heart failure.

10 In an article by Njemanze, entitled "Transcranial Doppler evaluation of syncope: An application in aerospace physiology," *Aviation Space Environmental Medicine*, June, 1991, 62(6), pp. 569-572, which is incorporated herein by reference, a non-invasive method is described which simultaneously measures mean arterial blood pressure, heart rate, and mean cerebral blood flow velocity in patients with a history of syncope, in horizontal and vertical postures. It is suggested that transcranial Doppler measurements may be used in aeromedical evaluation of syncope or syncopal tendency.

15 In another article, entitled "Cerebral and circulatory haemodynamics before vasovagal syncope induced by orthostatic stress," by Colier et al., *Clinical Physiology*, January, 1997, 17(1), pp. 83-94, which is incorporated herein by reference, a method is described for using near-infrared spectroscopy to assess cerebral oxygenation as an indicator of the onset of fainting.

20 In summary, an abrupt fall in blood pressure, including drug-induced, may result in a significant impairment in blood supply to one or more vital organs, such as the brain and/or heart. This situation will henceforth be termed Hemodynamic Compromise (HDC). HDC may generate a spectrum of morbid consequences at the level of various organs. These consequences may include one or more of the following cerebral manifestations: light-headedness, dizziness, faintness, fainting, vague ill-feeling, blindness, transient ischemic attack (TIA, i.e., transient neurologic impairment), stroke (permanent neurologic impairment), and probably multiple brain infarcts which may produce senile dementia. In addition, fainting may result in hip or spine fractures, which in elderly people are often fatal.

25 With respect to the heart, these consequences may include, among others, silent or overt angina pectoris, myocardial infarction, disturbances in cardiac rhythm putting the patient at risk of sudden death, and a variety of additional events.

Consequences at the level of the kidneys may include functional impairment of various degrees of severity.

All or part of these consequences will henceforth be termed Hemodynamic Compromise Associated Morbidity (HDCAM). It will be appreciated that although many examples are offered in the present patent application with respect to fainting, embodiments of the present invention can preferably be applied as well to all forms of HDCAM.

5 Hypertensive patients with or without comorbid conditions are at far greater risk of suffering HDCAM than normotensive individuals.

U.S. Patents 4,846,195, 5,354,317, 5,464,434, and 5,472,453, to Alt, describe the monitoring of the position or motion of a patient in order to provide an input to an implanted device, such as a pacemaker. U.S. Patent 5,724,983 to Selker et al., describes a method for 10 continuously monitoring a patient's condition, in order to determine whether to generate an alarm notification. U.S. Patent 5,865,760 to Lidman et al., describes a system for analyzing a patient's electrocardiogram in order to detect changes in body posture. All of these patents are incorporated herein by reference. PCT Patent Publication WO 00/47108 to Gafni et al., which is incorporated herein by reference, describes an ambulatory monitor which is designed to 15 increase patient compliance in taking medicine, and to report the side effects, symptoms, and effect of a treatment.

SUMMARY OF THE INVENTION

It is an object of some aspects of the present invention to provide improved apparatus and methods for monitoring physiological parameters of a patient so as to detect an abnormal 20 condition.

It is another object of some aspects of the present invention to provide improved apparatus and methods for monitoring a patient's blood pressure so as to detect an abnormal condition.

It is a further object of some aspects of the present invention to provide apparatus and 25 methods for preventing fainting.

It is yet a further object of some aspects of the present invention to provide apparatus and methods for detecting and/or preventing cardiac and/or cerebrovascular pathologies.

It is still a further object of some aspects of the present invention to provide apparatus and methods for monitoring physiological parameters of a patient so as to detect a pathological 30 situation resulting from hemodynamically-significant orthostatic hypotension.

In preferred embodiments of the present invention, a portable patient monitoring unit monitors the blood pressure of a patient, and additionally (and preferably simultaneously)

measures one or more other physiological parameters of the patient, so as to detect a form of HDC, such as a likelihood of the patient fainting. Preferably, the parameters include easily-measured indicators such as exertion, posture, respiration rate, an electroencephalographic (EEG) indicator, and/or an electrocardiographic (ECG) indicator. These and other parameters 5 are preferably used as early indicators of HDC. Further preferably, some or all of the data recorded by the portable patient monitoring unit are stored and periodically conveyed to the patient's physician, to enable the physician to determine behavior patterns of the patient which may precede hemodynamic compromise and/or to determine environmental conditions which may contribute to HDC. By understanding the behavior patterns or environmental conditions 10 which may bring on HDC in a particular patient, the physician is able to change aspects of the patient's therapy, such as drug dosage, type, or scheduling, and/or to recommend changes in the patient's daily routines, so as to reduce the likelihood of the HDC occurring.

Preferably, but not necessarily, when HDC is detected during regular operation of the monitoring unit, an alarm is generated. Typically, the alarm alerts the patient, such that s/he 15 can sit, lie down, or, if appropriate, seek treatment or modify a current treatment. Alternatively or additionally, a healthcare or emergency worker is advised of the onset of HDC.

It is to be understood that although avoiding fainting is described herein with respect to many preferred embodiments, many applications of the present invention are directed towards 20 using generally the same methods and apparatus, alternatively or additionally, for preventing and treating or for simply detecting other forms and/or effects of HDC. Further alternatively or additionally, these embodiments may be used to predict and/or prevent the ill-feeling associated with OH, which the inventor believes to be responsible for the non-compliance of many patients in following a regimen of anti-hypertensive medications. "Ill-feelings," or 25 unpleasant sensations experienced by the patient, are often vague, difficult-to-describe sensations, which may include dizziness, stomach upset, headache, or other relatively non-quantifiable sensations which, in combination, can be prevented or treated by these embodiments of the present invention. Preferably, the patient is enabled to enter into an electronic log of the portable monitoring unit a record of any ill-feelings or other symptoms s/he may experience. Subsequently, the physician and/or the portable monitoring unit itself 30 analyzes the electronic log in combination with the various physiological measurements in order to determine conditions which precede and/or cause HDC.

It is the inventor's belief that the significance and prevalence of OH in the hypertensive population have, hitherto, been largely underestimated by the medical community. According to current practice, blood pressure is typically measured in one position only, mostly sitting, so that the diagnosis of OH is missed all together. In addition, 5 the inventor believes that the OH diagnosis is missed in many cases because in any individual, and especially in drug treated hypertensive patients, blood pressure may vary considerably throughout the 24-hour period. Thus, clinically significant OH events, i.e., HDCAM, may happen at any time and cannot be predicted by a single measurement of supine and standing blood pressure in the doctor's office.

10 The accepted diagnosis of orthostatic hypotension traditionally requires a decline of about 20 mm Hg in systolic and/or 10 mm Hg in diastolic levels associated with the relevant change in position. However, the inventor believes that the likelihood of harmful consequences arising from the drop in blood pressure depends not only on the magnitude of the drop, but also on its abruptness and/or a number of other factors particular to the individual 15 patient's situation. These parameters may include one or more of the following: recent movements, time passed since sleeping, duration of sleeping, time since eating, blood sugar, ambient temperature and humidity etc. Moreover, even once these and/or other parameters are known, the likelihood of adverse consequences is highly dependent on characteristics of the individual patient.

20 For example, in a patient who suffers from significant narrowing of one or more of the main arteries supplying blood to the brain, a relatively-small decline in blood pressure in the upper part of the body may be sufficient to produce serious disturbances in brain function. Similarly, for patients suffering from narrowing of the coronary arteries, the near-simultaneous 25 occurrence of walking, or other exertion, with a fall in blood supply to the heart brought about by changing to the upright position, may disrupt cardiac function.

Therefore, the portable patient monitoring unit, according to some embodiments of the present invention, utilizes a broader understanding of orthostatic hypotension than is known in the art. Thus, as described herein, the monitoring unit typically evaluates a variety of physiological parameters, specific to the individual patient, including blood pressure, changes 30 in posture, and patient history, in order to determine the onset and severity of HDC.

In some preferred embodiments of the present invention, the monitoring unit analyzes changes in the patient's blood pressure, or rates of change of the blood pressure, in order to determine whether to generate the alarm. For example, a physiologically-significant blood

pressure drop or increase, or a rapid blood pressure drop or increase may indicate a likelihood of fainting or other HDCAM.

Preferably, the blood pressure measurement is combined with a determination of the patient's posture or changes thereof, so as to increase the precision with which the patient monitoring unit assesses and/or predicts HDC. For example, an indication that a drop in blood pressure occurred following a transition from the supine to the standing position may be used as an indication in some patients that fainting or another form of HDCAM is imminent. For these patients, the alarm generated responsive to these measurements might not have been generated based on only a blood pressure measurement, because of the large number of factors which contribute to a change in blood pressure that do not necessarily reflect or culminate in hemodynamic compromise. Optionally, the blood pressure and posture measurements are stored for an extended period, e.g., several hours, and data from the entire period are examined to determine the onset of hemodynamic compromise. Upon such a determination, an alarm or other notification is generated, and/or a drug treatment is initiated or modified.

There is therefore provided, in accordance with a preferred embodiment of the present invention, a method for continuously monitoring a patient, including:

measuring blood pressure of the patient, substantially without restricting the patient's movement;

measuring a physiological parameter of the patient; and

analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of the patient fainting.

Preferably, measuring the physiological parameter includes measuring a plurality of physiological parameters, including one or more of the following: electrocardiographic data, electroencephalographic data, an aspect of blood supply to the brain, heart and/or other organ of the patient, posture of the patient, motion of the patient, and an elapsed time since the patient ate.

Typically, analyzing the blood pressure includes analyzing a change in the blood pressure. Preferably, analyzing the change in the blood pressure includes at least one of: analyzing an increase in the blood pressure and analyzing a decrease in the blood pressure.

Alternatively or additionally, analyzing the change in the blood pressure includes analyzing a rate of change of the blood pressure. Further alternatively or additionally, analyzing the change in the blood pressure includes analyzing a pattern of change of the blood pressure.

In a preferred embodiment, measuring the physiological parameter of the patient includes measuring the physiological parameter at a first time, wherein measuring the blood pressure includes measuring the blood pressure at a second time, at least 1 minute subsequent to the first time, and wherein analyzing the blood pressure in combination with analyzing the physiological parameter includes analyzing in combination the physiological parameter measured at the first time and the blood pressure measured at the second time. Preferably, the second time is at least 1 hour subsequent to the first time.

In a preferred embodiment, the method includes recording an environmental parameter, wherein analyzing the blood pressure in combination with analyzing the physiological parameter includes analyzing the blood pressure in combination with analyzing the physiological parameter and in combination with analyzing the environmental parameter. Typically, the environmental parameter includes at least one of: temperature, humidity, ambient light, and time of day.

Preferably, but not necessarily, the method includes providing a treatment responsive to detecting the likelihood of fainting. For example, providing the treatment may include administering a pharmaceutical product to the patient. Alternatively or additionally, providing the treatment includes inflating medical anti-shock trousers worn by the patient.

Preferably, the method includes notifying a person responsive to detecting the likelihood of fainting. For some applications, notifying the person includes causing a message to be transmitted to a location not in an immediate vicinity of the patient. In these applications, the method typically includes determining a location of the patient, wherein causing the message to be transmitted includes transmitting data responsive to the determined location of the patient.

Alternatively or additionally, the method includes measuring and analyzing the blood pressure and the physiological parameter during a calibration period, so as to determine a threshold value for notifying the person, wherein analyzing so as to detect the likelihood of the patient fainting includes generating a regular operation period sample value responsive to the blood pressure and the physiological parameter measured during a regular operation period, and wherein notifying the person includes evaluating the regular operation period sample value with respect to the threshold value.

Preferably, the method includes:

receiving during the calibration period an input from the patient indicating an onset of light-headedness and/or any other relevant symptom; and

determining the threshold value responsive to the input from the patient.

For some applications of the present invention, notifying the person includes notifying the patient, for example, by causing a light to turn on or generating an audible signal containing a vocal message. Alternatively or additionally, notifying the person includes 5 notifying an appropriate person (such as a healthcare worker) or an appropriate organization. Preferably, notifying the healthcare worker includes transmitting to the healthcare worker data indicative of a physiological state of the patient and/or data indicative of a location of the patient.

There is still further provided, in accordance with a preferred embodiment of the 10 present invention, a method for monitoring a patient, including:

measuring blood pressure of the patient, substantially without restricting the patient's movement;

measuring a physiological parameter of the patient; and

15 analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of myocardial infarction.

There is yet further provided, in accordance with a preferred embodiment of the present invention, a method for monitoring a patient, including:

measuring blood pressure of the patient, substantially without restricting the patient's movement;

20 measuring a physiological parameter of the patient; and

analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of any cardiac impairment such as angina pectoris.

There is additionally provided, in accordance with a preferred embodiment of the present invention, a method for monitoring a patient, including:

25 measuring blood pressure of the patient, substantially without restricting the patient's movement;

measuring a physiological parameter of the patient; and

analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of the patient experiencing dizziness.

30 There is still additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for monitoring a patient, including:

a blood pressure sensor, adapted to repeatedly measure blood pressure of the patient substantially without restricting motion of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

5 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient experiencing dizziness.

There is yet additionally provided, in accordance with a preferred embodiment of the present invention, a method for monitoring a patient, including:

10 measuring blood pressure of the patient, substantially without restricting the patient's movement;

measuring a physiological parameter of the patient; and

analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of the patient having an ill-feeling or fainting.

15 There is also provided, in accordance with a preferred embodiment of the present invention, a method for monitoring a patient, including:

measuring blood pressure of the patient, substantially without restricting the patient's movement;

measuring a physiological parameter of the patient; and

20 analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of a cardiac rhythm disturbance.

There is further provided, in accordance with a preferred embodiment of the present invention, a method for monitoring a patient, including:

measuring blood pressure of the patient, substantially without restricting the patient's movement;

25 measuring a physiological parameter of the patient; and

analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of sudden death of the patient.

There is still further provided, in accordance with a preferred embodiment of the present invention, a method for monitoring a patient, including:

30 measuring blood pressure of the patient, substantially without restricting the patient's movement;

measuring a physical disposition of the patient; and

analyzing the blood pressure in combination with analyzing the physical disposition, so as to detect an abnormal condition of the patient.

Preferably, measuring the physical disposition of the patient includes measuring posture of the patient, motion of the patient, and/or a level of physical exertion of the patient.

5 Alternatively or additionally, analyzing so as to detect the abnormal condition includes analyzing so as to detect hemodynamic compromise. In a preferred embodiment, analyzing so as to detect hemodynamic compromise includes analyzing so as to detect a likelihood of the patient fainting.

10 In a preferred embodiment, the method includes providing a treatment responsive to detecting the abnormal condition.

There is yet further provided, in accordance with a preferred embodiment of the present invention, apparatus for monitoring a patient, including:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

15 a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient fainting.

20 Preferably, the physiological parameter sensor includes a plurality of physiological parameter sensors. In a preferred embodiment, the physiological parameter sensor includes electrocardiographic apparatus and/or electroencephalographic apparatus and/or any apparatus to assess, preferably continuously, the function of and/or blood supply to the brain, heart or other relevant organ.

25 In a preferred embodiment, the apparatus includes transmitter, wherein the control unit is adapted to actuate the transmitter to transmit a signal, so as to cause a light to turn on responsive to detecting the likelihood of the patient fainting.

30 Alternatively or additionally, the apparatus includes a loudspeaker, wherein the control unit is adapted to actuate the loudspeaker to generate an audible signal responsive to detecting the likelihood of the patient fainting. Typically, the control unit is adapted to actuate the loudspeaker to generate a vocal message.

In a preferred embodiment, the physiological parameter sensor includes a physical disposition sensor, such as a posture sensor, a motion sensor, and/or a sensor which is adapted to sense a level of physical exertion of the patient.

Preferably, the control unit includes a transmitter, which is adapted to transmit a signal to a location not in an immediate vicinity of the patient, responsive to detecting the likelihood of the patient fainting. Typically, the control unit includes a location transducer, which is adapted to determine a location of the patient, and the transmitter is adapted to transmit the signal responsive to the determined location of the patient. Preferably, the control unit is adapted to actuate the transmitter to transmit data indicative of a physiological state of the patient.

In a preferred embodiment, the apparatus includes an environmental parameter transducer, adapted to convey to the control unit an environmental parameter signal responsive to a parameter of the environment, wherein the control unit is adapted to analyze the blood pressure signal in combination with analyzing the physiological parameter signal and in combination with analyzing the environmental parameter signal.

In a preferred embodiment, the apparatus includes a treatment unit, coupled to the control unit, wherein the control unit is adapted to actuate the treatment unit to administer a treatment to the patient responsive to detecting the likelihood of fainting. The treatment unit may include a pharmaceutical delivery unit or medical anti-shock trousers.

There is also provided, in accordance with a preferred embodiment of the present invention, apparatus for monitoring a patient, including:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

a physical disposition sensor, adapted to measure a physical disposition of the patient; and

a control unit, adapted to receive respective blood pressure and physical disposition signals from the blood pressure sensor and the physical disposition sensor, and to analyze the signals in combination, so as to detect an abnormal condition of the patient.

Preferably, the control unit is adapted to analyze the signals in combination so as to detect hemodynamic compromise.

In a preferred embodiment, the control unit is adapted to receive from the patient an input signal indicative of the patient feeling an unpleasant sensation, and the control unit is adapted to analyze the input signal in combination with the signal from the blood pressure

sensor and the physical disposition sensor, so as to detect the abnormal condition of the patient.

There is additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for monitoring a patient, including:

5 a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

10 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of myocardial infarction.

There is still additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for monitoring a patient, including:

15 a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

20 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of angina pectoris.

There is yet additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for monitoring a patient, including:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

25 a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient experiencing 30 ill-feeling.

There is also provided, in accordance with a preferred embodiment of the present invention, apparatus for monitoring a patient, including:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

5 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of a cardiac rhythm disturbance.

There is further provided, in accordance with a preferred embodiment of the present
10 invention, apparatus for monitoring a patient, including:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

15 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of sudden death of the patient.

There is still further provided, in accordance with a preferred embodiment of the
20 present invention, apparatus for monitoring a patient, including:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting motion of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

25 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient having a stroke.

The present invention will be more fully understood from the following detailed
30 description of the preferred embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of patient monitoring apparatus, in accordance with a preferred embodiment of the present invention; and

Fig. 2 is a schematic block diagram illustrating details of the patient monitoring apparatus of Fig. 1, in accordance with a preferred embodiment of the present invention.

5

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 is a schematic illustration of patient monitoring apparatus 20, used for monitoring the blood pressure and at least one other physiological parameter of a patient 50, in accordance with a preferred embodiment of the present invention. Apparatus 20 preferably comprises a control unit 30, coupled to receive signals from a blood pressure monitor 40 and 10 at least one sensor 22, and to store these for later review by the patient's physician.

Preferably, the blood pressure monitor measures the patient's blood pressure according to a schedule designed to minimize discomfort to the patient and interference with the patient's activities of daily living. Further preferably, the blood pressure measurement substantially does not interfere with the patient's movement. Thus, for example, blood pressure 15 measurements may be taken in an automatic or semi-automatic mode at any of the places the patient may visit during a day (e.g., home, shopping, office), while the patient is supine, sitting, walking, or engaged in substantially any other activity. The patient is thus preferably not limited to having blood pressure and other measurements made only in a healthcare facility.

20 The control unit preferably processes the signals from blood pressure monitor 40 and sensor 22, in order to determine the likelihood of the onset of an abnormal condition such as fainting and/or other form of HDCAM, as described hereinbelow with reference to Fig. 2. Typically, sensor 22 comprises at least one physical disposition sensor 42, which conveys data to the control unit responsive to the posture, motion, and/or exertion of patient 50. 25 Alternatively or additionally, sensor 22 comprises electrocardiograph electrodes 44 and electroencephalograph electrodes 46. Further alternatively or additionally, sensor 22 comprises one or more other sensors known in the art (not shown), such as an ultrasound Doppler sensor, a pulse oximeter, and/or a cardiac output monitor, which convey to the control unit signals reflecting an aspect of the cardiovascular health of patient 50.

30 Fig. 2 is a schematic block diagram illustrating details of control unit 30, in accordance with a preferred embodiment of the present invention. Preferably, control unit 30 comprises a processor 70, which is coupled to a memory 72, a battery 74, a radio transmitter 62, a radio

receiver 64, a global positioning system (GPS) block 60, an environmental sensor 78, an active therapeutic unit 24, user controls 32, and an alarm output 76 for notifying patient 50 and/or an emergency or healthcare worker upon the detection of the onset of an abnormal physiological condition of the patient.

5 A calibration period of apparatus 20 is preferably provided for applications of the present invention in which control unit 30 actuates alarm output 76 to warn the patient of the onset of hemodynamic compromise. The calibration is typically performed in the presence of the patient's physician or under the supervision of a remote physician (e.g., by tele-medicine). During the calibration period (and, when appropriate, during regular operation of apparatus 10 20), processor 70 generates a profile of patient 50, including her sensitivity to changes in the various parameters measured by control unit 30. For some applications, the calibration period can be relatively short, while for others, the patient may stay overnight in a healthcare facility. In a preferred embodiment, the patient changes position from supine to erect, and is asked to press a button on user controls 32 when she begins to feel dizzy, light-headed, or otherwise not 15 completely normal. Blood pressure readings from monitor 40, position readings from physical disposition sensor 42, and optionally other readings from one or more of the other sensors are preferably recorded prior to, during, and subsequent to the change of position, and are stored in memory 72. Thereafter, the physician or processor 70 compares the recorded data with the inputs entered through the user controls, so as to determine characteristics of various 20 combinations of the measurements which are indicative of imminent fainting or of the onset of any other type of HDCAM.

Preferably, this or a similar calibration procedure is repeated under many different conditions, e.g., at different times of the day, at various times following eating, under a range 25 of temperature, humidity and lighting conditions, and immediately upon the patient waking from sleep as well as while the patient is fully alert. In this manner, processor 70 "learns" the thresholds at which patient 50 begins to feel light-headed, in a set of situations that the patient is likely to encounter and which often indicate the beginning of HDC. For each of the conditions tested, the physician or the processor preferably sets a regular-operation alarm threshold, which is lower than that at which the patient herself senses the HDC. For example, 30 during calibration of apparatus 20, the patient may indicate through user controls 32 a feeling of light-headedness after waking and immediately standing up. If the act of standing up is associated with a drop in the measured systolic pressure from 140 mm Hg to 80 mm Hg, then the regular-operation alarm threshold for the transition from laying down to standing may be

set such that alarm output 76 is activated due to a drop of only 30 mm Hg. In addition, it is believed that in some patients HDC may be engendered following blood pressure changes which are significantly smaller than changes known in the art to produce orthostatic hypotension (20 mm Hg systolic and 10 mm Hg diastolic), particularly when these changes are 5 accompanied by changes in some of the other physiological indicators described herein.

In a subsequent calibration or regular-operation monitoring period, patient 50 may indicate to processor 70 a feeling of light-headedness in a hot and humid environment, even up to one or two hours following standing up from a sitting position. Processor 70 preferably records in memory 72 any changes in blood pressure or in the other sensed physiological 10 parameters associated with the reported sensation, so as to determine an alarm threshold corresponding thereto. As appropriate, short-term measures (e.g., sounding an alarm or administering a drug) and/or long-term measures (e.g., changing the patient's diet, drug regimen, or instructing the patient in OH-reducing practices) are taken responsive to the data stored in memory 72.

15 It is noted that in some patients, a drop in blood pressure associated with a particular posture or posture change may be sufficient to reliably trigger processor 70 to actuate alarm output 76 prior to a fainting episode. In other patients, however, a combination of one or more of the following indicators are preferably assessed, sometimes for a period of 24 hours, in order to determine whether to actuate the alarm output:

20

- an increase or a decrease of the patient's blood pressure,
- a rate of change or other characteristic of the blood pressure,
- the patient's posture (e.g., supine, sitting, standing),
- the patient's movement and/or level of exertion, typically as measured by one or more accelerometers in physical disposition sensor 42,

25

- input from EEG electrodes 46, ECG electrodes 44, or substantially any sensor known in the art for measuring a cardiovascular or other physiological parameter,
- elapsed time since eating, drinking, sleeping, and taking medicines,
- environmental conditions detected by sensor 78, such as temperature, humidity, time of day, ambient light, and

30

- patient history.

In order to treat the detected hemodynamic compromise, e.g., to prevent a fainting episode which is determined to be occurring or imminent, alarm output 76 preferably generates a very loud tone, to warn the patient that she should sit or lay down immediately.

The loss of consciousness, which otherwise would have occurred, is often prevented due to the patient reassuming her prior posture, possibly in combination with an autonomic response to the loud tone itself. Alternatively or additionally, processor 70 actuates alarm output 76 to repeatedly play a recorded message, such as, "You must sit down immediately," until physical disposition sensor 42 conveys a signal indicating that the patient is sitting or laying down, or until the hemodynamic compromise has substantially diminished. Alternatively, even if patient 50 does faint, the warning she received from apparatus 20 preferably enabled her to sit or lie down, thereby minimizing or eliminating severe injuries commonly associated with unexpected loss of consciousness in some patient populations.

Because the potentially-harmful effects of orthostatic hypotension are believed to generally depend not only on the magnitude of the decline of blood pressure, but also on a number of additional factors, an HDC scoring system is preferably generated for each patient, based on data generated during the calibration period and/or during regular operation of monitoring apparatus 20. Thus, an individual's HDC score typically varies continuously, based on the automatic analysis by control unit 30 of the data conveyed thereto. In a preferred embodiment, a ranking of 1 (least severe) to 5 (most severe) is assigned to a plurality of factors, such as one or more drawn from the following list:

- blood pressure,
- body position and changes thereof,
- magnitude of physical exertion,
- pathological changes in electrocardiographic (ECG) pattern, indicating impairment of blood supply to the heart,
- evidence of impairment of blood supply to the brain,
- patient risk factors such as previous cerebrovascular or cardiac ischemic events, and
- duration and/or frequency of any abnormal measurements.

Typically, the HDC score is then determined by adding or otherwise combining the rankings. Preferably, high values of the HDC score and/or abrupt increases thereof, are used as a trigger to cause control unit 30 to generate an alarm. Alternatively or additionally, the patient's physician uses the high HDC score as grounds for introducing changes in the patient's therapy, for initiating the use of auxiliary preventative measures, or for suggesting that the patient adopt appropriate lifestyle changes.

Because fainting and other forms of hemodynamic compromise often occur when a susceptible patient gets out of bed during the middle of the night, processor 70 preferably

actuates radio transmitter 62 to transmit an alarm signal to a receiver (not shown) in the patient's home, which is programmed to turn on lights responsive to receiving the signal. It is believed that turning on the lights benefits the patient by enhancing the warning of the audible alarm signal, thereby increasing the chance that the possibly confused or dizzy patient will 5 attempt to sit or lie down. It is also possible that turning on the lights, in and of itself, may cause an autonomic response in the patient, which increases her blood pressure and reduces the likelihood of fainting or otherwise terminates the HDCAM.

For some applications, apparatus 20 is additionally configured to alert a healthcare worker based on settings stored in memory 72 during the calibration period and/or during 10 regular operation of the apparatus. For example, if patient 50 is a nursing-home resident, then processor 70 may actuate radio transmitter 62 to issue a notification to a receiver at a nurses' station each time that imminent fainting or other HDCAM is detected. Upon receiving the notification, a nurse can transmit queries to processor 70 or oral instructions to the patient, which are received by radio receiver 64. As appropriate, the processor responds to the queries, 15 by transmitting, for example, the most recent 15 minutes of data from the various sensors. Alternatively or additionally, if the patient's location is unknown, the nurse's query can specify that the output of GPS block 60 be coded and transmitted.

In a preferred embodiment, the healthcare worker, or processor 70 by itself, is enabled 20 to actuate active therapeutic unit 24, so as to treat or mitigate the HDCAM, e.g., by preventing an expected fainting episode or reducing its severity. Depending on the patient's condition, active therapeutic unit 24 may comprise an automatic device for inflating medical anti-shock trousers, a drug-delivery unit, or other apparatus known in the art for restoring blood pressure or otherwise preventing fainting. Typically, active therapeutic unit 24 is actuated 25 automatically by processor 70 if the patient lives at home or is out of the house, while unit 24 is typically actuated by a healthcare worker if the patient lives in a nursing-home or other controlled environment.

For patients outside of a hospital or nursing-home setting, it may be impractical to alert 30 a healthcare worker whenever hemodynamic compromise is detected. For these patients, settings in memory 72 preferably cause processor 70 to recognize a situation in which, following activation of alarm output 76, there is an indication by physical disposition sensor 42 that there has been a sudden change in position of the patient from standing up to lying down, optionally followed by a period of substantially no movement by patient 50. Responsive to this indication of the patient having fallen down, or to signals from any of the

sensors which indicate a pathological condition of patient 50, processor 70 preferably actuates radio transmitter 62 to convey an alarm signal to a communication unit (not shown) coupled to a telephone in the patient's house, or to a cellular telephone carried by the patient. Responsive thereto, the communication unit actuates the telephone to dial an emergency phone number, 5 such as that of an ambulance dispatcher or a nearby relative. Alternatively or additionally, the communication unit causes an e-mail or other type of message to be sent over the Internet, so as to call for help. For some patients, it is desirable to provide apparatus for the ambulance dispatcher to enable him to send queries or instructions to processor 70, as described hereinabove.

10 In a preferred embodiment, data stored in memory 72 are conveyed to the patient's physician on a regular basis. Preferably, the physician reviews the data so as to determine whether to recommend changes in management of the patient's medical condition. For example, it may be determined that the patient should take certain medications closer to meal times, or that, after waking up, she should always lie in bed for several minutes before 15 attempting to sit up.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove and in the articles and patents incorporated herein by reference, as well 20 as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

CLAIMS

1. A method for monitoring a patient, comprising:
 - measuring blood pressure of the patient, substantially without restricting movement of the patient;
 - 5 measuring a physiological parameter of the patient; andanalyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of the patient fainting.
2. A method according to claim 1, wherein measuring the physiological parameter comprises measuring a plurality of physiological parameters.
- 10 3. A method according to claim 1, wherein measuring the physiological parameter comprises recording electrocardiographic data.
4. A method according to claim 1, wherein measuring the physiological parameter comprises recording electroencephalographic data.
- 15 5. A method according to claim 1, wherein measuring the physiological parameter comprises measuring an aspect of blood supply to a brain of the patient.
6. A method according to claim 1, wherein measuring the physiological parameter comprises determining posture of the patient.
7. A method according to claim 1, wherein measuring the physiological parameter comprises measuring motion of the patient.
- 20 8. A method according to claim 1, wherein measuring the physiological parameter comprises determining an elapsed time since the patient ate.
9. A method according to any one of claims 1 - 8, wherein analyzing the blood pressure comprises analyzing a change in the blood pressure.
- 25 10. A method according to claim 9, wherein analyzing the change in the blood pressure comprises at least one of: analyzing an increase in the blood pressure and analyzing a decrease in the blood pressure.
11. A method according to claim 9, wherein analyzing the change in the blood pressure comprises analyzing a rate of change of the blood pressure.
12. A method according to claim 9, wherein analyzing the change in the blood pressure comprises analyzing a pattern of change of the blood pressure.
- 30 13. A method according to any one of claims 1 - 8, wherein measuring the physiological parameter of the patient comprises measuring the physiological parameter at a first time,

wherein measuring the blood pressure comprises measuring the blood pressure at a second time, at least 1 minute subsequent to the first time, and wherein analyzing the blood pressure in combination with analyzing the physiological parameter comprises analyzing in combination the physiological parameter measured at the first time and the blood pressure measured at the second time.

5 14. A method according to claim 13, wherein measuring the blood pressure at the second time comprises measuring the blood pressure at least 1 hour subsequent to the first time.

10 15. A method according to any one of claims 1 - 8, and comprising recording an environmental parameter, wherein analyzing the blood pressure in combination with analyzing the physiological parameter comprises analyzing the blood pressure in combination with analyzing the physiological parameter and in combination with analyzing the environmental parameter.

15 16. A method according to claim 15, wherein recording the environmental parameter comprises recording at least one of: temperature, humidity, ambient light, and time of day.

17. A method according to any one of claims 1 - 8, and comprising providing a treatment responsive to detecting the likelihood of fainting.

18. A method according to claim 17, wherein providing the treatment comprises administering a pharmaceutical product to the patient.

19. A method according to claim 17, wherein providing the treatment comprises inflating 20 medical anti-shock trousers worn by the patient.

20. A method according to any one of claims 1 - 8, and comprising notifying a person responsive to detecting the likelihood of fainting.

21. A method according to claim 20, wherein notifying the person comprises causing a message to be transmitted to a location not in an immediate vicinity of the patient.

22. A method according to claim 21, and comprising determining a location of the patient, wherein causing the message to be transmitted comprises transmitting data responsive to the determined location of the patient.

23. A method according to claim 20, and comprising measuring and analyzing the blood pressure and the physiological parameter during a calibration period, so as to determine a 30 threshold value for notifying the person, wherein analyzing so as to detect the likelihood of the patient fainting comprises generating a regular operation period sample value responsive to the blood pressure and the physiological parameter measured during a regular operation period,

and wherein notifying the person comprises evaluating the regular operation period sample value with respect to the threshold value.

24. A method according to claim 23, and comprising:

receiving during the calibration period an input from the patient indicating an onset of

5 light-headedness; and

determining the threshold value responsive to the input from the patient.

25. A method according to claim 20, wherein notifying the person comprises notifying the patient.

26. A method according to claim 25, wherein notifying the patient comprises causing a 10 light to turn on.

27. A method according to claim 25, wherein notifying the patient comprises generating an audible signal.

28. A method according to claim 27, wherein generating the audible signal comprises generating a vocal message.

15 29. A method according to claim 20, wherein notifying the person comprises notifying a healthcare worker.

30. A method according to claim 29, wherein notifying the healthcare worker comprises transmitting to the healthcare worker data indicative of a physiological state of the patient.

20 31. A method according to claim 29, wherein notifying the healthcare worker comprises transmitting to the healthcare worker data indicative of a location of the patient.

32. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

measuring a physiological parameter of the patient; and

25 analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of the patient having a stroke.

33. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

30 measuring a physiological parameter of the patient; and

analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of myocardial infarction.

34. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

measuring a physiological parameter of the patient; and

5 analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of angina pectoris.

35. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

measuring a physiological parameter of the patient; and

10 analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of the patient experiencing dizziness.

36. Apparatus for monitoring a patient, comprising:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

15 a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

20 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient experiencing dizziness.

37. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

measuring a physiological parameter of the patient; and

25 analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of the patient having an ill-feeling.

38. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

30 measuring a physiological parameter of the patient; and

analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of a cardiac rhythm disturbance.

39. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

measuring a physiological parameter of the patient; and

5 analyzing the blood pressure in combination with analyzing the physiological parameter, so as to detect a likelihood of sudden death of the patient.

40. A method for monitoring a patient, comprising:

measuring blood pressure of the patient, substantially without restricting movement of the patient;

measuring a physical disposition of the patient; and

10 analyzing the blood pressure in combination with analyzing the physical disposition, so as to detect an abnormal condition of the patient.

41. A method according to claim 40, wherein measuring the physical disposition of the patient comprises measuring posture of the patient.

15 42. A method according to claim 40, wherein measuring the physical disposition of the patient comprises measuring motion of the patient.

43. A method according to claim 40, wherein measuring the physical disposition of the patient comprises measuring a level of physical exertion of the patient.

44. A method according to any one of claims 40 - 43, wherein analyzing so as to detect the abnormal condition comprises analyzing so as to detect hemodynamic compromise.

20 45. A method according to claim 44, wherein analyzing so as to detect hemodynamic compromise comprises analyzing so as to detect a likelihood of the patient fainting.

46. A method according to any one of claims 40 - 43, and comprising notifying a person responsive to detecting the abnormal condition.

25 47. A method according to claim 46, wherein notifying the person comprises causing a message to be transmitted to a remote location.

48. A method according to claim 46, wherein notifying the person comprises notifying the patient.

49. A method according to any one of claims 40 - 43, and comprising recording an environmental parameter, wherein analyzing the blood pressure in combination with analyzing the physical disposition comprises analyzing the blood pressure in combination with analyzing the physical disposition and in combination with analyzing the environmental parameter.

30 50. A method according to any one of claims 40 - 43, and comprising providing a treatment responsive to detecting the abnormal condition.

51. A method according to any one of claims 40 - 43, wherein measuring the physical disposition of the patient comprises measuring the physical disposition at a first time, wherein measuring the blood pressure comprises measuring the blood pressure at a second time, at least 1 minute subsequent to the first time, and wherein analyzing the blood pressure in 5 combination with analyzing the physical disposition comprises analyzing in combination the physical disposition measured at the first time and the blood pressure measured at the second time.

52. A method according to claim 51, wherein measuring the blood pressure at the second time measuring the blood pressure at least 15 minutes subsequent to the first time.

10 53. Apparatus for monitoring a patient, comprising:
a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;
a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and
15 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient fainting.

54. Apparatus according to claim 53, wherein the physiological parameter sensor comprises a plurality of physiological parameter sensors.

20 55. Apparatus according to claim 53, wherein the physiological parameter sensor comprises electrocardiographic apparatus.

56. Apparatus according to claim 53, wherein the physiological parameter sensor comprises electroencephalographic apparatus.

25 57. Apparatus according to any one of claims 53 - 56, wherein the control unit is adapted to notify a person responsive to detecting the likelihood of the patient fainting.

58. Apparatus according to claim 57, wherein the control unit is adapted to notify the patient responsive to detecting the likelihood of the patient fainting.

59. Apparatus according to claim 57, wherein the control unit is adapted to notify a healthcare worker responsive to detecting the likelihood of the patient fainting.

30 60. Apparatus according to claim 57, wherein the control unit comprises an input unit, adapted to receive during a calibration period an input from the patient indicating an onset of light-headedness, wherein the control unit is adapted to receive calibration period blood pressure and physiological parameter signals during the calibration period, and to determine a

threshold value for notifying the person, responsive to the calibration period signals and the input from the patient, and wherein the control unit is adapted to notify the person during a regular operation period responsive to the blood pressure signal, the physiological parameter signal, and the threshold value.

5. 61. Apparatus according to any one of claims 53 - 56, wherein the physiological parameter sensor is adapted to measure the physiological parameter of the patient at a first time, wherein the blood pressure sensor is adapted to measure the blood pressure at a second time, at least 1 minute subsequent to the first time, and wherein the control unit is adapted to analyze in combination the physiological parameter measured at the first time and the blood pressure measured at the second time.

10. 62. Apparatus according to claim 61, wherein the blood pressure sensor is adapted to measure the blood pressure at the second time, at least 15 minutes subsequent to the first time.

15. 63. Apparatus according to any one of claims 53 - 56, and comprising a transmitter, wherein the control unit is adapted to actuate the transmitter to transmit a signal, so as to cause a light to turn on responsive to detecting the likelihood of the patient fainting.

64. Apparatus according to any one of claims 53 - 56, and comprising a loudspeaker, wherein the control unit is adapted to actuate the loudspeaker to generate an audible signal responsive to detecting the likelihood of the patient fainting.

20. 65. Apparatus according to claim 64, wherein the control unit is adapted to actuate the loudspeaker to generate a vocal message.

66. Apparatus according to any one of claims 53 - 56, wherein the physiological parameter sensor comprises a physical disposition sensor.

67. Apparatus according to claim 66, wherein the physical disposition sensor comprises a posture sensor.

25. 68. Apparatus according to claim 66, wherein the physical disposition sensor comprises a motion sensor.

69. Apparatus according to claim 66, wherein the physical disposition sensor comprises a sensor which is adapted to sense a level of physical exertion of the patient.

70. Apparatus according to any one of claims 53 - 56, wherein the control unit is adapted 30 to determine a change in the blood pressure and to analyze the determined change in combination with the physiological parameter signal, so as to detect the likelihood of fainting.

71. Apparatus according to claim 70, wherein the control unit is adapted to perform at least one of: an analysis to determine an increase in the blood pressure and an analysis to determine a decrease in the blood pressure.

72. Apparatus according to claim 70, wherein the control unit is adapted to analyze a rate of change of the blood pressure.

73. Apparatus according to any one of claims 53 - 56, wherein the control unit comprises a transmitter, which is adapted to transmit a signal which is received at a location not in an immediate vicinity of the patient, responsive to detecting the likelihood of the patient fainting.

74. Apparatus according to claim 73, wherein the control unit comprises a location transducer, which is adapted to determine a location of the patient, and wherein the transmitter is adapted to transmit the signal responsive to the determined location of the patient.

75. Apparatus according to claim 73, wherein the control unit is adapted to actuate the transmitter to transmit data indicative of a physiological state of the patient.

76. Apparatus according to any one of claims 53 - 56, and comprising an environmental parameter transducer, adapted to convey to the control unit an environmental parameter signal responsive to a parameter of the environment, wherein the control unit is adapted to analyze the blood pressure signal in combination with analyzing the physiological parameter signal and in combination with analyzing the environmental parameter signal.

77. Apparatus according to claim 76, wherein the environmental parameter transducer is adapted to convey the environmental parameter signal to the control unit responsive to at least one of: temperature, humidity, ambient light, and time of day.

78. Apparatus according to any one of claims 53 - 56, and comprising a treatment unit, coupled to the control unit, wherein the control unit is adapted to actuate the treatment unit to administer a treatment to the patient responsive to detecting the likelihood of fainting.

79. Apparatus according to claim 78, wherein the treatment unit comprises a pharmaceutical delivery unit.

80. Apparatus according to claim 78, wherein the treatment unit comprises medical anti-shock trousers.

81. Apparatus for monitoring a patient, comprising:

30 a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

31 a physical disposition sensor, adapted to measure a physical disposition of the patient; and

a control unit, adapted to receive respective blood pressure and physical disposition signals from the blood pressure sensor and the physical disposition sensor, and to analyze the signals in combination, so as to detect an abnormal condition of the patient.

82. Apparatus according to claim 81, wherein the physical disposition sensor is adapted to 5 measure posture of the patient.

83. Apparatus according to claim 81, wherein the physical disposition sensor is adapted to measure motion of the patient.

84. Apparatus according to claim 81, wherein the physical disposition sensor is adapted to measure a level of physical exertion of the patient.

10 85. Apparatus according to any one of claims 81 - 84, wherein the control unit is adapted to analyze the signals in combination so as to detect hemodynamic compromise.

86. Apparatus according to claim 85, wherein the control unit is adapted to analyze the signals in combination so as to detect a likelihood of the patient fainting.

15 87. Apparatus according to any one of claims 81 - 84, wherein the control unit comprises a transmitter, which is adapted to transmit a signal which is received at a location not in an immediate vicinity of the patient, responsive to detecting the abnormal condition.

20 88. Apparatus according to any one of claims 81 - 84, and comprising an environmental parameter transducer, adapted to convey to the control unit an environmental parameter signal responsive to a parameter of the environment, wherein the control unit is adapted to analyze the blood pressure signal in combination with analyzing the physical disposition signal and in combination with analyzing the environmental parameter signal.

89. Apparatus according to any one of claims 81 - 84, and comprising a treatment unit, coupled to the control unit, wherein the control unit is adapted to actuate the treatment unit to administer a treatment to the patient responsive to detecting the abnormal condition.

25 90. Apparatus according to any one of claims 81 - 84, wherein the control unit is adapted to notify a person responsive to detecting the abnormal condition.

91. Apparatus according to claim 90, wherein the control unit is adapted to notify the patient responsive to detecting the abnormal condition.

30 92. Apparatus according to any one of claims 81 - 84, wherein the physical disposition sensor is adapted to measure the physical disposition of the patient at a first time, wherein the blood pressure sensor is adapted to measure the blood pressure at a second time, at least 1 minute subsequent to the first time, and wherein the control unit is adapted to analyze in

combination the physical disposition measured at the first time and the blood pressure measured at the second time.

93. Apparatus according to any one of claims 81 - 84, wherein the control unit is adapted to receive from the patient an input signal indicative of the patient feeling an unpleasant sensation, and wherein the control unit is adapted to analyze the input signal in combination with the signal from the blood pressure sensor and the physical disposition sensor, so as to detect the abnormal condition of the patient.

94. Apparatus for monitoring a patient, comprising:

10 a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

15 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of myocardial infarction.

95. Apparatus for monitoring a patient, comprising:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

20 a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of angina pectoris.

96. Apparatus for monitoring a patient, comprising:

25 a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

30 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient experiencing ill-feeling.

97. Apparatus for monitoring a patient, comprising:

a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

5 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of a cardiac rhythm disturbance.

98. Apparatus for monitoring a patient, comprising:

10 a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

15 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of sudden death of the patient.

99. Apparatus for monitoring a patient, comprising:

20 a blood pressure sensor, adapted to measure blood pressure of the patient substantially without restricting movement of the patient;

a physiological parameter sensor, adapted to measure a physiological parameter of the patient; and

25 a control unit, adapted to receive respective blood pressure and physiological parameter signals from the blood pressure sensor and the physiological parameter sensor, and to analyze the signals in combination, so as to detect a likelihood of the patient having a neurological disorder.

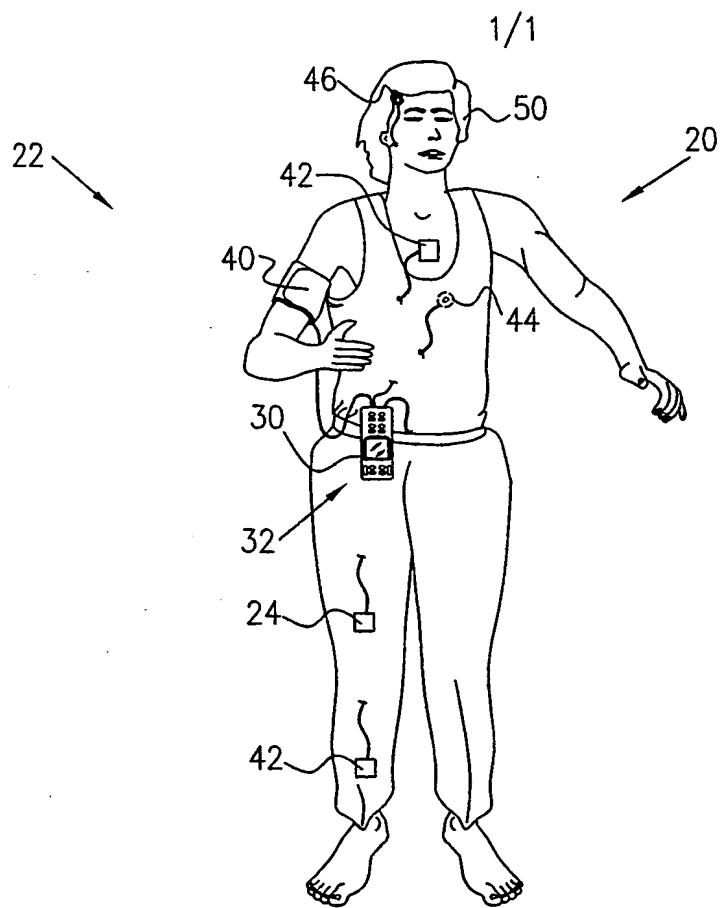


FIG. 1

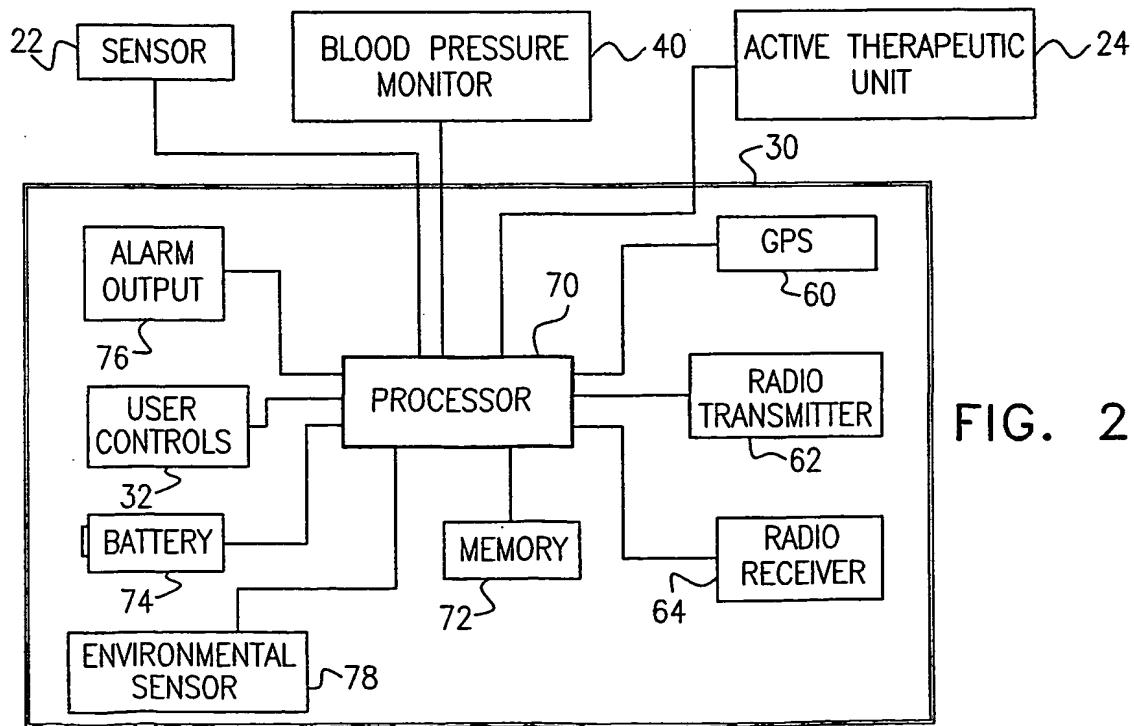


FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 01/01072

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0205

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 43537 A (TELECOM MEDICAL INC) 8 October 1998 (1998-10-08) page 3, line 3-14 page 18, line 9-30 page 19, paragraph 2 ---	36,53, 55, 57-59, 63,69, 70,73, 81-85,87
X	WO 00 40145 A (CRITICARE SYSTEMS INC) 13 July 2000 (2000-07-13) page 17, line 4 -page 20, line 16 ---	36,53, 55, 57-59, 63,69, 70,73, 94-99

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

18 March 2002

Date of mailing of the international search report

26/03/2002

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.
Fax: (+31-70) 340-3016

Authorized officer

Papone, F

INTERNATIONAL SEARCH REPORT

Inte
nal Application No
PCT/IL 01/01072

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 00056 A (VITALCOM INC) 8 January 1998 (1998-01-08) page 8, line 41 -page 7, line 2; figure 1 ---	36, 53, 94-99
A	US 4 958 645 A (CADELL THEODORE E ET AL) 25 September 1990 (1990-09-25) claim 4 ---	36, 53, 81, 94-99
A	WO 00 62664 A (BRIEN WILLIAM G O ;LLEWELLYN MICHAEL D (GB); MULLARKEY WILLIAM J () 26 October 2000 (2000-10-26) page 6, line 21-29 page 19, line 26 -page 20, line 2 ---	36, 53, 55, 57-59, 63, 69, 70, 73
A	US 6 147 618 A (HALLECK MICHAEL D ET AL) 14 November 2000 (2000-11-14) column 18, line 5.21 ---	81

INTERNATIONAL SEARCH REPORT

nation on patent family members

International Application No

PCT/IL 01/01072

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
WO 9843537	A 08-10-1998	AU EP WO	6943698 A 0973437 A1 9843537 A1	22-10-1998 26-01-2000 08-10-1998
WO 0040145	A 13-07-2000	AU WO	2405100 A 0040145 A1	24-07-2000 13-07-2000
WO 9800056	A 08-01-1998	US AU WO US US US	5944659 A 3129297 A 9800056 A1 6213942 B1 2001023315 A1 2001034475 A1	31-08-1999 21-01-1998 08-01-1998 10-04-2001 20-09-2001 25-10-2001
US 4958645	A 25-09-1990	NONE		
WO 0062664	A 26-10-2000	AU EP WO	4642300 A 1176905 A1 0062664 A1	02-11-2000 06-02-2002 26-10-2000
US 6147618	A 14-11-2000	US AU WO AU WO US US US	6307481 B1 2744401 A 0150433 A1 7586700 A 0120571 A1 2001000431 A1 2001048368 A1 2002008630 A1	23-10-2001 16-07-2001 12-07-2001 17-04-2001 22-03-2001 26-04-2001 06-12-2001 24-01-2002